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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,846	08/31/2000	Timothy Hla	UCT-0012	4421

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EXAMINER	
SCHMIDT, MARY M	

ART UNIT	PAPER NUMBER
1635	19

DATE MAILED: 07/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/651,846	Applicant(s) HLA ET AL.	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-82 is/are pending in the application.

4a) Of the above claim(s) 41-53,62-72 and 79-82 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 33-40,54-61 and 73-78 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The non-elected claims 41-53, 62-72 and 79-82 are withdrawn from consideration in view of the election by original presentation in the Office Action mailed 4/15/02, Paper #15.

Claim Rejections - 35 USC § 102

3. Claims 33-35, 54-56 and 73-75 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO9919513/ N_Geneseq_1101 database accession number AAX36573 (July 07, 1999) for the same reasons of record as set forth in the Official Action mailed 2/15/02.

Applicant's arguments filed 5/14/02 have been fully considered but they are not persuasive.

Claims 33-34, 54-55 and 73 as amended are drawn to: any antisense composition which inhibits the expression of a nucleic acid molecule encoding a human EDG-1 or EDG-3 receptor, and any antisense oligonucleotide wherein the antisense oligonucleotide hybridizes to a nucleic acid encoding an EDG-1 or EDG-3 receptor and wherein the antisense oligonucleotide includes the translational initiation site of the EDG-1 or EDG-3 receptor. Claims 35, 56 and 74-75 further specify an oligonucleotide comprising SEQ ID NO:1 or 2.

Applicant argues that the EDG-1 primer taught in WO9918513/N_Geneseq_1101 does not teach the sequence of instant SEQ ID No: 1 and states that "[t]his oligonucleotide does not encompass instant SEQ ID NO:1 as instant SEQ ID NO:1 is an antisense oligonucleotide."

However, as demonstrated in the comparison search of instant SEQ ID NO:1 and Geneseq AAX36573, there is an identical base sequence "gacgctggtgggccccat" in common, which corresponds to bases 1-18 of instant SEQ ID NO:1 and bases 15-32 of the EDG-1 primer taught by Geneseq AAX36573. The EDG-1 primer taught by the prior art thus inlcudes within it the entire sequence of instant SEQ ID NO:1, and as such, anticipates the composition of SEQ ID NO:1, as a nucleic acid sequence which binds to the same region of the EDG-1 gene as instant SEQ ID NO:1. As argued previously, MPEP 2112.01 taught that "if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." As such, the antisense properties of the claimed sequence of SEQ ID NO:1 are inherently found in the teachings of the prior art, Geneseq AAX36573.

Similarly, Applicant argues that Geneseq AAX36573 does not read on instant SEQ ID NO:2. However, as shown in the alignment of instant SEQ ID NO:2 with Geneseq AAX36573, 100% of instant SEQ ID NO:2 is found within the EDG-3 primer sequence in Geneseq AAX36573, specifically, the sequence "gctggtgggccccatggt". As such, and in view of MPEP2112.01, the sequence in Geneseq AAX36573 anticipates the sequence of instant SEQ ID NO:2.

Since the prior art which teaches instant SEQ ID NO:1 and SEQ ID NO:2 includes the initiation codon of EDG-1 and EDG-3, the new limitations to claims 33, 54, and 73 are met by the prior art cited herein.

Claim Rejections - 35 USC § 103

4. Claims 33-40, 54-61 and 73-78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO9919513 for the reasons stated above in view of either of Baracchini et al. (U.S. Patent 5,801,154) or Cowsert (U.S. Patent 5,951,455) for the same reasons of record as set forth in the Official Action mailed 2/15/02.

Applicant's arguments filed 5/14/02 have been fully considered but they are not persuasive.

Applicant's arguments against the teachings of WO9929531 (the "Erikson" patent, the original source for the sequences of Geneseq AAX36573) have been traversed above. Since the sequences of Geneseq AAX36573 include 100% identical regions to instant SEQ ID Nos. 1 and 2, they necessarily anticipate the instant SEQ ID Nos. 1 and 2, and absent evidence to the contrary, would function as antisense to EDG-1 and EDG-3 accordingly.

Applicant further argues that "Erikson teach sense primers that bind EDG-1 and EDG-3 under the conditions of a PCR reaction, but fail to teach antisense oligonucleotides that inhibit the expression of an EDG gene under "native" conditions. There is no teaching in Erikson that would suggest that the initiation codon of EDG-1 or EDG-3 would be available for binding an antisense oligonucleotide under native structural conditions. Applicants thus submit that there is no teaching in... Erikson of antisense to EDG-1 and EDG-3 that inhibit the expression of an EDG gene and wherein the antisense oligonucleotide includes the translation initiation codon. Further, there is no teaching in ... Erikson to suggest that the translation initiation codon of EDG-1 or EDG-3 would be available for antisense oligonucleotide binding." Applicants further argue that

"Baracchini and Cowsert do not cure the defect. Both references are directed to antisense compositions to genes other than EDG genes. While both Baracchini and Cowsert are directed to antisense compositions, neither provides any teaching to suggest that the initiation codon of the EDG genes would be available for antisense oligonucleotide binding. Neither reference provides teachings as to which regions of EDG-1 and EDG-3 would be suitable targets for antisense oligonucleotides."

In response, the pending claims, claims 33-40, 54-61 and 73-78 are drawn to antisense compositions, and not to methods of using the claimed compositions in cells. Claim 34, for instance, claims an antisense oligonucleotide of claim 34 which hybridizes to a nucleic acid molecule encoding an EDG-1 receptor. Since the function of antisense is characteristic of the claimed nucleic acid structures, and antisense is broadly interpreted in the art as the complementary sequence of a sense sequence, and nucleic acid antisense sequences bind to the complementary sense sequence via Watson-Crick interactions, one of ordinary skill in the art would have recognized that the antisense functions of the claimed oligonucleotides, when given this plain meaning, were met by the prior art. Specifically, the claims did not describe the conditions of binding of the antisense oligonucleotides, the claims read on binding in any condition, including the isolated binding in a buffer as in a PCR reaction. Such a binding would also be considered antisense binding or hybridizing. Therefore, the prior art compositions, absent evidence to the contrary would function for antisense oligonucleotide inhibition of gene function.

Thus it is not significant that the Baracchini and Cowsert references do not teach antisense to EDG genes since they were relied upon to teaching modifications of antisense oligonucleotides common in the art and suitable for use on the primer sequences to EDG-1 and EDG-3 taught by WO9929531 (the original source for the sequences of Geneseq AAX36573). One of ordinary skill in the art would have recognized the use of the teachings of Baracchini and Cowsert for the modification of antisense to target regions for the optimized results taught therein.

Applicant's argue that there was no expectation of success that the EDG-1 and EDG-3 primers would function "[a]s is well known in the antisense art, particular sequences may be inaccessible to binding by antisense oligonucleotides either due to RNA structure or the presence of RNA binding proteins." However, as admitted by Application, the primers taught in the prior art did function in PCR reactions, and taught that they did bind to the target gene. Further, in view of the fact that the claims are given their broadest reasonable interpretation, the claims do not suggest use of the antisense in any particular environment. Thus the claims embrace use of the antisense as antisense sequences in any environment, at least one portion of which is considered to allow for binding of SEQ ID NO:1 and/or 2 to the target gene sequences. Since the conditions of environments in vitro may be manipulated just as the conditions of a PCR reaction may be manipulated, one of skill in the art would have recognized that there was an expectation of success for the sequences taught in the prior art to function in some capacity as an antisense nucleic acid, and bind the target EDG-1 or EDG-3 genes. Furthermore, an *in vitro* reaction not in

cells, for instance, would not necessarily have RNA structure or the presence of binding proteins, and thus would have a expectation for the functional limitation to be met.

For these reasons, one of ordinary skill in the art would have recognized that it was *prima facie* obvious at the time the invention was made to make the claimed nucleic acid compositions.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 29, 2002

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600